REMARKS

The abstract is objected-to because the Examiner states that it should not refer to speculative merits and the title is objected to because it is not descriptive. Both bases of objection are traversed. MPEP 608.01(b) states that the purpose of abstract is to enable the public to quickly determine the gist of the disclosure. The present abstract does exactly that. No amendment is required. The words of the title are found verbatim in claim 1 (now claim 9). Nothing more descriptive is required, the Examiner's stylistic choice of alternative language notwithstanding.

Claims 6 and 7 are rejected under 35 USC 112 as indefinite. In new claims 14-16, it is made clear that the amounts refer to the core and the coating, respectively, as supported by pages 2 and 3 of the specification. Claims 15 and 16 also combine canceled claims 7 and 8 by incorporating titanium dioxide into the definition of the coating. Claims 15 and 16 also recite "w/w", which is deemed to be inherent in the specification.

Claims 1-3 and 5-7 are rejected as obvious over USP 6,558,701 ("US'701"). The rejection is traversed. The teaching of US'701 is totally irrelevant to the present invention. US'701 teaches a multilayer (minimum of three) tablet with two active ingredients and an internal separation layer. This layer is quite different from a coating. Coatings are mentioned only in passing in US'701 as optional embodiments. Nothing is said about the composition or function of these optional coatings, other can that they may be applied by conventional processes. The coatings are mentioned only in the plural, not in the singular, as is required in the present invention. In fact, a single coating produces a surprising and unexpected advantage by the claimed combination of materials in the present coating, as described n the specification, in particular in the data of the comparative table. Since the reference itself distinguishes between the separation layer and the coatings, the Examiner cannot equate the two, as she has done in the parenthetical insertion at the middle of page 4 of the Action. Further, since the reference teaches nothing about these optional coatings other than their application by conventional processes, nothing that the reference teaches about the composition of the separation layer can be transferred to the coatings. Furthermore, even if the teaching regarding the separation layer could be applied to the

coating, the amounts of disclosed components such as MCC and HPMC are completely outside the scope of the corresponding compounds of the present invention. The Examiner herself recognizes the limited relevance of US'701 by stating that the reference does not teach diclofenac in the core, that it does not teach that the diclofenac-containing layer is coated, and that the reference does not teach stearic acid. Notwithstanding these significant differences between US'701 and the present invention, the Examiner nevertheless concludes that it would be obvious "to prepare a tablet with more than 3 layers or with diclofenac in the core" to arrive at a coated diclofenac tablet. This conclusion is totally without basis in the reference.

The Examiner continues the rejection by arguing that "optimization of parameters" would lead to the desired result. This basis of rejection is also traversed. If the Examiner persists in the argument, it is requested that she specifically identify where in US'701 it is suggested to delete one of the two active ingredients, where in the reference it is suggested that the composition of the separation layer be applied to the optional coatings, where in the reference it is suggested that the coatings are not to be optional, where in the reference it is suggested that by radically altering the composition of the separation layer a coating can be achieved that exhibits the unexpected benefits of the present invention, and that she otherwise specifically recite what guidance US'701 provides to the practitioner to lead to the "desired result". It is noted that the Examiner only recites hardness and compressibility as a desired result, neither of which are claimed to be properties of the present invention.

Claims 1-7 are rejected under 35 USC 103 as obvious over US'701 as applied to claims 1-3 and 5-7 and further in view of US 6,083,531 ("US'531"). The rejection is traversed and the combination of the two references is deemed to be without basis. The comments provided above with regard to US'701 are repeated. First, it is noted that the Examiner again mistakenly identifies the separating layer of US'701 with the optional coatings of US'701, two components which US'701 specifically distinguish from each other. The combination of the references is deemed to be without merit because they are directed to two totally different dosage forms. In the case of US'701, a multilayer tablet comprising two active ingredients separated by an intermediate layer is disclosed. The patent makes passing reference to optional coatings for which no further details are provided. In the case of US'531, a mixture, especially a homogenous mixture, of four components selected for rapid disintegration is disclosed. The tablet cannot be coated since this would negate the

rapid dissolve property provided by the selected components. Other than both disclose drug dosage forms, the two teachings are not at all related. Not being related, there is no basis for the combination. And even if one were to combine a multilayer tablet with a homogenous mixture of four components, one would not arrive at the coated tablet of the present invention.

Claims 1-3 and 5-8 are rejected under 35 USC 103 over US'701 as applied to claims 1-3 and 5-7 and further in view of US 4,341,563 ("US'563"). The rejection is traversed. The comments provided above with regard to US'701 are repeated. First, it is noted that the Examiner again mistakenly identifies the separating layer of US'701 with the optional coatings of US'701, two components which US'701 specifically distinguish from each other. Further, the Examiner mistakenly asserts that US'701 teaches stearic acid whereas she has already stated on page 4 of the Action that it does not. Also, whether or not titanium dioxide is taught in the separating layer of US'701 is irrelevant since there is no separating layer in the present invention. Referring now to US'536, this reference distinguishes between stearic acid and its salts and points out the disadvantage known in the art of using stearic acid because of the inevitable need to use an organic solvent therewith. In the "Reference" examples, where stearic acid is used, microcrystalline cellulose (which is an essential element of the present coating) is never used. In fact, MCC is never referred to in US'536. The Examiner concludes that from these reference it would be obvious to prepare a multilayer tablet. Applicants traverse this conclusion, but even if it were correct, that is not the claimed invention. She also concludes that it would be obvious to add the TiO_2 of US'536 to the coating of US'701, but this is also incorrect since there is no teaching in US'701 as to the composition of the optional coatings therein, so it cannot be obvious to add anything to said coatings.

Claims 1, 2, and 5-7 are rejected as unpatentable over WO 99/51209 (WO'209"). Although no statutory basis is stated for the rejection, in the interest of compact prosecution, it is assumed that a rejection under 35 USC 103 is intended. It is requested that the Examiner verify this or provide some other basis for the rejection. The rejection is traversed. The teaching of WO'209 has no relevance to the present invention. WO'209 teaches a two-(optionally three-) compartment dosage form consisting of 1) an innermost (when present) compartment containing no active ingredient but only polymers, 2) a next compartment containing active and polymers for immediate release of an active, and 3) a surrounding

outermost, "extended release" compartment containing active and a combination of hydrophobic and hydrophilic polymers designed to retard release of the active in said and the next inner compartments, but to retain the shape of the drug delivery system for some extended period of time. Ignoring the inert innermost core, the other two compartments each contain a combination of active drug and polymers. Besides the fact that the structure of the reference is totally different from that of the present invention, no mention is made therein of diclofenac potassium, even though well over 100 active compounds are listed, including many in salt form. Even if diclofenac potassium is not viewed as having been deliberately excluded from WO'209, it certainly cannot be said to be obvious therefrom.

Again the Examiner continues the rejection by arguing that "optimization of parameters" would lead to the desired result. This basis of rejection is also traversed. If the Examiner persists in the argument, it is requested that she specifically recite what guidance WO'209 provides to the practitioner to lead to the "desired result", especially in view of the fact that an extended release outer compartment is not one of the objectives of the present invention. It is noted that the Examiner only recites hardness and compressibility as a desired result, neither of which are presently claimed to be properties of the present invention.

Claims 1-7 are also rejected under 35 USC 103 as obvious over WO'209 in view of US'531. In the body of the argument, the Examiner also relies on US'701 and it is assumed that this reference was inadvertently omitted from the first paragraph of point 12. The rejection is traversed. The comments provided above with regard to all three references are repeated. There is no basis for combining these three references since no combination of the multilayer tablet of US'701, the uncoated four-component, rapidly dissolving tablet of US'531, and the dosage form of WO'209 which comprises an extended release outermost compartment could possibly lead one to the coated tablet of the present invention. Merely because they are all concerned with the tableting art and disclose similar or overlapping components is not the basis for a rejection under the statute.

Claims 1-8 are also rejected under 35 USC 103 as obvious over WO'209 in view of US'531 and US'563. The rejection is traversed. The comments provided above with regard to all three references are repeated. There is no basis for combining the first two references since no combination of the dosage form of WO'209 which comprises an extended release

outermost compartment and the uncoated four-component, rapidly dissolving tablet of US'531, could possibly lead one to the coated tablet of the present invention. The disclosure of various ingredients by US'563 does nothing to cure this basic deficiency in combining the first two references since the teaching of any additional ingredients could not possibly lead one to proceed from the first two references to the present invention.

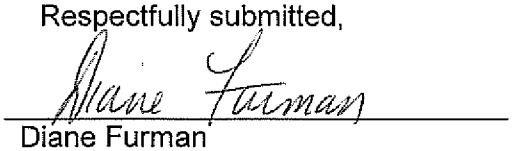
It is requested that the amendments be entered and that the Examiner reconsider the objections and rejections in view of the amendments and remarks and that the case be passed to issue.

Should the Examiner believe that a telephonic interview with applicant's undersigned attorney would advance the status of this prosecution, she is respectfully invited to contact the undersigned at the below-indicated telephone number.

Fees

Applicants request that any additional claim fees, or other fees necessitated by this paper, be charged to Deposit Account No. 50-4395 in the name of Novartis Consumer Health, Inc.

Respectfully submitted,



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